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# 法律法规简报

## Legal Update

### 2025-08



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## 1. 国家药监局就医疗器械相关规定征求意见 2025.07.31 NMPA Seeks Comments on the Medical Device Related Provisions

为规范互联网药品医疗器械信息服务备案，加强互联网药品医疗器械信息服务管理，国家药监局组织起草了《互联网药品医疗器械信息服务备案管理规定（征求意见稿）》（下称“《管理规定》”），现向社会公开征求意见，意见截至 2025 年 8 月 30 日。

In order to standardize the filing of internet drug and medical device information services to strengthen the administration of internet drug and medical device information services, the National Medical Products Administration (NMPA) has drafted the *Administrative Provisions on the Filing of Internet Drug and Medical Device Information Services (Draft for Comment)* (the “*Administrative Provisions*”). The *Administrative Provisions* is hereby released for public comment until August 30<sup>th</sup>, 2025.

《管理规定》明确了在中华人民共和国境内通过互联网为上网用户提供药品和医疗器械信息服务活动应当适用此规定，且互联网药品医疗器械信息服务的备案应当以网站或者移动互联网应用程序为基本单元。《管理规定》列举了主要责任义务包括提供互联网药品医疗器械信息服务的网站或者移动互联网应用程序，应当在首页或者主页面的显著位置持续公示互联网药品医疗器械信息服务备案编号。登载的药品医疗器械信息，必须真实、准确、完整，并符合国家药品和医疗器械管理相关规定，提供互联网药品医疗器械信息服务的网站或者移动互联网应用程序的主办单位，应当指定至少一名熟悉药品、医疗器械管理法律、法规的管理人员负责合规管理，定期对网站或者移动互联网应用程序所登载的药品医疗器械信息组织开展合规性评价，确保登载的药品医疗器械信息持续合规等。

The *Administrative Provisions* specifies that the provision of drug and medical device information services to internet users within the territory of the People's Republic of China via the internet shall be governed by the provisions, and websites or mobile internet applications shall be adopted as the basic units in the filing of internet drug and medical device information services. The *Administrative Provisions* stipulates primary responsibilities and obligations, including a website or mobile internet application providing internet drug and medical device information services shall continuously publicize the filing number of its internet drug and medical device information services in a prominent position on its website's homepage. The information published about drugs and medical devices shall be authentic, accurate, complete, and comply with national regulations on the administration of drugs and



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medical devices. The organizer of a website or mobile internet application providing internet drug and medical device information services shall designate at least one manager familiar with laws and regulations on the administration of drugs and medical devices to be responsible for compliance management work. Such manager shall regularly organize compliance evaluations of the drug and medical device information published on the website or mobile internet application to ensure continuous compliance of such information.

为规范和指导医疗器械网络销售质量管理规范现场检查工作，国家药监局组织起草了《医疗器械网络销售质量管理规范现场检查指导原则(征求意见稿)》(下称“《原则》”)，现向社会公开征求意见，意见截至 2025 年 8 月 30 日。《原则》列明检查内容及检查要点，并对关键项目与一般项目进行区分，对网络销售经营者、电商平台经营者分别提出不同要求。

To standardize and guide the on-site inspection of quality management practices for online medical device sales, the NMPA has drafted the *Guidelines Principles for Quality Management On-site Inspections of Online Sale of Medical Devices (Draft for Comment)* (the “Principles”). The *Principles* is hereby released for public comment until August 30<sup>th</sup>, 2025. The *Principles* specifies the inspection content and key points, differentiate between critical and general items, and set forth distinct requirements for online sellers and e-commerce platform operators.

(Source: <https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjylqx/20250731154819162.html>  
<https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjylqx/20250806151011128.html>)

## 2. 司法部就修订《行政复议法实施条例》征求意见 2025.08.04 **MOJ Seeks Comments on Implementation Regulations for the Administrative Reconsideration Law**

为进一步健全行政复议体制机制，提高行政复议工作质效，司法部起草了《中华人民共和国行政复议法实施条例(修订征求意见稿)》(下称“《条例征求意见稿》”)，现向社会公开征求意见，意见截至 2025 年 9 月 3 日。

In order to further improve the institutional mechanisms for administrative reconsideration and enhance the quality and efficiency, the Ministry of Justice (MOJ) has recently released the *Implementation Regulations for the Law of the People's Republic of China on Administrative Reconsideration (Revision Draft for Comment)* (the “Draft Regulations”). The *Draft Regulations* is hereby released for public comment until September 3<sup>rd</sup>, 2025.



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原条例共七章六十六条，《条例征求意见稿》增至八章八十六条，修改内容主要如下：（一）进一步明确行政复议法总则部分要求；（二）进一步细化申请行政复议的相关规定；（三）进一步规范行政复议案件办理；（四）进一步健全行政复议指导和监督。此外，《条例征求意见稿》在健全了行政复议办案尽职免责机制，完善了行政复议与同级监察机关的衔接机制，并明确了特殊领域行政复议案件的法律适用问题。

The original Regulations consists of seven chapters and 66 articles and the *Draft Regulations* has expanded to eight chapters and 86 articles. The main revisions include: (1) further specifying certain requirements set out in the General Provisions of the *Administrative Reconsideration Law*; (2) refining provisions related to the filing of administrative reconsideration applications; (3) standardizing procedures for the handling of administrative reconsideration cases; (4) improving the mechanisms for the guidance and supervision of administrative reconsideration. In addition, the *Draft Regulations* improves the duty-fulfillment liability exemption mechanism in handling administrative reconsideration cases, enhances the coordination mechanism between administrative reconsideration organs and supervision agencies at the same level, and clarifies the application of law for administrative reconsideration cases in special fields.

(Source:

[https://www.moj.gov.cn/pub/sfbgw/lfyjzj/lflfyjzj/202508/t20250804\\_523412.html](https://www.moj.gov.cn/pub/sfbgw/lfyjzj/lflfyjzj/202508/t20250804_523412.html))

### 3. 国家矿山安监局印发《矿山安全风险监测预警处置工作管理办法》2025.08.08 NMSA Issues Administrative Measures for Monitoring, Early Warning, and Response to Mine Safety Risks

为进一步加强和规范矿山安全风险监测预警处置工作，国家矿山安全监察局组织制定了《矿山安全风险监测预警处置工作管理办法（试行）》（下称“《管理办法》”），自 2025 年 11 月 1 日起执行。

To further strengthen and standardize the monitoring, early warning, and response to mine safety risks, the National Mine Safety Administration has formulated the *Administrative Measures for Monitoring, Early Warning, and Response to Mine Safety Risks (Trial)* (the “*Administrative Measures*”), which shall come into effect on November 1<sup>st</sup>, 2025.



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《管理办法》共六章二十三条，包括总则、工作责任、预警信息等级划分、预警信息处置、监督检查、附则。矿山及上级企业、矿山安全监管监察部门利用各类矿山安全生产监测预警信息化系统开展的风险监测、预警响应、分析研判、核查反馈等工作，适用《管理办法》。监测预警处置工作坚持国家监察、地方监管、企业负责。按照“分类分级、科学规范、及时处置、闭环管理”的原则，建立以矿山及上级企业为主体，矿山安全监管监察部门既各负其责、又协同配合的工作机制，实现系统共用、数据共享，形成横向联动、纵向贯通的工作体系。

The *Administrative Measures* consists of six chapters and 23 articles, comprising General Provisions, Work Responsibilities, Classification of Early-Warning Information, Response to Early-Warning Information, Supervision and Inspection, and Supplementary Provisions. The *Administrative Measures* shall apply to the monitoring of risks, response to early warnings, analysis and assessment, verification and feedback, and other related work carried out by mines and the superior companies, as well as mine safety supervision departments through various information monitoring and early-warning systems for mine safety production. The work of monitoring, early-warning, and response adheres to the principle of national supervision, local regulation, and enterprise responsibility. In accordance with the principle of “categorized and hierarchical management, scientific standardization, timely response, and closed-loop management”, a working mechanism shall be established with mines and the superior companies as the main entities, and mine safety supervision departments each assuming their own responsibilities while also coordinating and cooperating, which aims to achieve shared systems and data interoperability, forming a work system characterized by horizontal coordination and vertical integration.

(Source:

[https://www.chinamine-safety.gov.cn/zfxxgk/fdzdgknr/tzgg/202508/t20250813\\_554349.shtml](https://www.chinamine-safety.gov.cn/zfxxgk/fdzdgknr/tzgg/202508/t20250813_554349.shtml))

#### 4. 网安标委就《个人信息保护国家标准体系》等征求意见 2025.08.15 TC260 Seeks Comments on the National Personal Information Protection Standards System and Other Drafts

为更好发挥数据安全标准化工作的基础性、规范性、引领性作用，网安标委发布了《个人信息保护国家标准（2025版）（征求意见稿）》《数据安全国家标准体系（2025版）（征求意见稿）》，以更好指导下一步数据安全和个人



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信息保护国家标准研制，为有效保障数据安全、促进数字经济高质量发展提供安全标准依据。

To better leverage the fundamental, normative, and guiding role of data security standardization work, the National Technical Committee 260 on Cybersecurity Standardization Administration of China (TC260) has issued the *National Personal Information Protection Standards System (2025 Edition) (Draft for Comment)* and, the *National Data Security Standards System (2025 Edition) (Draft for Comment)* which aim to provide improved guidance for the development of future national standards for data security and personal information protection, thereby offering a security standards foundation for effectively safeguarding data security and promoting the high-quality development of the digital economy.

《个人信息保护国家标准（2025 版）（征求意见稿）》依据个人信息保护政策法规，综合考虑个人信息保护在监督管理、产业规范、问题风险、技术发展、国际接轨等方面的标准化需求，建立健全个人信息保护国家标准体系。

The *National Personal Information Protection Standards System (2025 Edition) (Draft for Comment)* is established based on relevant policies and regulations for personal information protection, taking into comprehensive consideration the standardization needs in areas such as supervision and management, industry regulation, issue and risk mitigation, technological development, and international alignment. This framework aims to build and refine a robust national standard system for personal information protection.

《数据安全国家标准体系（2025 版）（征求意见稿）》依据数据安全政策法规，综合考虑国家数据安全治理、企业数据安全能力提升、数据安全技术产业发展、数据安全问题风险防范、数据安全国际标准转化等标准化需求，建立健全数据安全国家标准体系。

The *National Data Security Standards System (2025 Edition) (Draft for Comment)* is established based on data security policies and regulations, comprehensively considering standardization requirements including national data security management, enhancement of corporate data security capabilities, development of the data security technology industry, prevention of data security issues and risks, and the adoption of international data security standards. This initiative seeks to establish and strengthen a comprehensive national standard system for data security.

(Source:

<https://www.tc260.org.cn/front/postDetail.html?id=20250731172556>)



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## 5. 两办推进绿色低碳转型加强全国碳市场建设 2025.08.25 **Two Offices Promote Green and Low-carbon Transformation and Strengthen the National Carbon Market Development**

碳市场是利用市场机制积极应对气候变化、加快经济社会发展全面绿色转型的重要政策工具。为推动建设更加有效、更有活力、更具国际影响力的全国碳市场，中共中央办公厅及国务院办公厅提出《关于推进绿色低碳转型加强全国碳市场建设的意见》（下称“《意见》”）。

The carbon market constitutes a vital policy tool that utilizes market mechanisms to actively address climate change and accelerate the green transformation of economic and social development. To promote the construction of a more effective, dynamic, and internationally influential national carbon market, the General Office of the CPC Central Committee and the General Office of the State Council issued the *Opinions on Promoting Green and Low-Carbon Transformation and Strengthening the Construction of the National Carbon Market* (the “*Opinions*”).

《意见》提出到 2027 年，全国碳排放权交易市场基本覆盖工业领域主要排放行业，全国温室气体自愿减排交易市场实现重点领域全覆盖。到 2030 年，基本建成以配额总量控制为基础、免费和有偿分配相结合的全国碳排放权交易市场。为达成以上目标，《意见》明确应加快建设全国碳排放权交易市场、积极发展全国温室气体自愿减排交易市场、着力提升碳市场活力、全面加强碳市场能力建设等。

The *Opinions* proposes that by 2027, the national carbon emission trading market should essentially cover all major emitting industries in the industrial sector, and the national voluntary greenhouse gas emission reduction trading market should achieve full coverage in key sectors. By 2030, a national carbon emission trading market shall be fundamentally established, based on total quota control and incorporating both free and paid allocation mechanisms. To achieve these objectives, the *Opinions* specifies that the national carbon emission trading market construction should be accelerated, the national voluntary greenhouse gas emission reduction trading market should be actively developed, the vitality of the carbon market should be enhanced, carbon market capacity building should be comprehensively strengthened, etc.

(Source: [https://www.gov.cn/zhengce/202508/content\\_7037717.htm](https://www.gov.cn/zhengce/202508/content_7037717.htm))



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